



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

***Mononegavirales* vectors expressing chimeric antigens**

Description of Technology:

Human respiratory syncytial virus (RSV) continues to be the leading viral cause of severe acute lower respiratory tract disease in infants and children worldwide, and also is an important cause of morbidity and mortality in the elderly. A licensed vaccine or antiviral drug suitable for routine use remains unavailable. This invention relates to the use of murine pneumonia virus (MPV - previously known as pneumonia virus of mice, PVM - of family *Pneumoviridae*) as a vaccine vector expressing the RSV fusion protein F, the most important protective antigen of RSV. MPV is not a human pathogen and is not restricted by immunity to common human viruses. MPV replicates in the superficial epithelial cells of the respiratory mucosa and is expected to be attenuated in humans based on the strong host range restriction observed in non-human primates. To generate these MPV/RSV vector vaccine candidates, the RSV F ORF was codon optimized, placed under the control of MPV transcription signals, and inserted at the first (rMPV-F1), third (rMPV29 F3), or fourth (rMPV-F4) gene position of a version of the MPV genome that contained a codon-pair optimized L polymerase gene. The recovered viruses replicated *in vitro* as efficiently as the empty vector, with stable expression of RSV F protein. Replication and immunogenicity of rMPV-F1 and rMPV-F3 were evaluated in rhesus macaques following administration by the combined intranasal and intratracheal routes. Both viruses replicated at low levels in the upper and lower respiratory tract, maintained stable RSV F expression, and induced similarly high levels of RSV-neutralizing serum antibodies that reached peak titers by fourteen (14) days post-vaccination. Thus, rMPV provides a highly attenuated yet immunogenic vector for the expression of RSV F protein, with potential application in RSV-naïve and RSV-experienced populations. RSV F was expressed in the wild-type form, but can readily be engineered to be stabilized in the highly immunogenic prefusion form, as has been done with parainfluenza virus vectors.

The invention relates to live, chimeric non-human *Mononegavirales* vectors that allow a cell to express at least one protein from at least one human pathogen as well as compositions comprising the vectors, methods and kits for eliciting an immune response in a host, and methods of making the vectors.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Viral diagnostics
- Vaccine research

Competitive Advantages:

- Ease of manufacture
- Multivalent live attenuated vaccines
- B cell and T cell activation
- Low-cost vaccines

Development Stage:

- In vivo data assessment (animal)

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Intellectual Property: HHS Reference No. E-018-2018/0—U.S. Provisional Application No. 62/661,320, filed April 23, 2018 (expired), PCT Patent Application No. PCT/US2019/028771, filed April 23, 2019 (expired), Taiwanese Patent Application No. 108114132, filed April 23, 2019 (pending), Brazilian Patent Application No. BR112020021652-6, filed October 22, 2020 (pending), Australian Patent Application No. 2019261570, filed October 21, 2020 (pending), Canadian Patent Application No. 3097888, filed October 20, 2020 (pending), Chinese Patent Application No.

201980039372.6, filed December 15, 2020 (pending), European Patent Application No. 19729386.3, filed November 13, 2020 (pending), Indian Patent Application No. 20204706248, filed October 23, 2020, Japanese Patent Application No. 2020-558967, filed October 22, 2020, South Korean Patent Application No. 2020-7033157, filed November 18, 2020, and United States Patent Application No. 17/049,916, filed October 22, 2020.

Licensing Contact: Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov.

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